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IN THE
Supreme Court of the United States
OCTOBER TERM, 1985

FRANK YOUNG,
Commissioner of Food and Drugs,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF AMICUS CURIAE NATIONAL FOOD PROCESSORS ASSOCIATION

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BRIEF OF AMICUS CURIAE NATIONAL FOOD PROCESSORS ASSOCIATION

INTEREST OF AMICUS CURIAE

Amicus submits this brief in support of the petitioner Frank Young, Commissioner of Food and Drugs. Consent to file this brief has been obtained from counsel for all parties and has been filed with the Clerk of this Court.

The National Food Processors Association ("NFPA") is a scientifically based trade association representing almost 600 member-companies that pack a broad range of processed-prepared food products for distribution throughout the country and the world. A substantial portion of these pro-

cessed products are prepared from fruits, vegetables, and other raw agricultural commodities which in their growing state are exposed to unintended and unavoidable contaminants in the natural environment and which thereby contain extremely small but detectable levels of any number of such environmental contaminants that generally cannot be removed by processing operations. The detection, identification, and possible reduction of these environmental contaminants in raw and processed foods has for many years been an important aspect of the work carried on in the three scientific laboratories of NFPA.[1]

The food processor members of NFPA and the Association itself would thus be very substantially affected by an interpretation of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. §§ 301-392 (1982) ("the Act") that regards as adulterated all foods containing detectable amounts of any unavoidable environmental contaminant unless and until a formal tolerance has been established for each such contaminant in a broad range of agricultural commodities pursuant to costly, burdensome, and time-consuming evidentiary hearing procedures.

[1]The Association was founded in 1907 as the National Canners Association, growing out of the collective canning industry support for enactment of the Food and Drug Act of 1906. Since its first scientific research laboratory was opened in 1913 the Association has been actively involved in research, testing and training programs that contribute significantly to the safety of the food supply. The Association has continuously maintained its interest in food safety legislation and regulatory programs, including the Federal Food, Drug, and Cosmetic Act of 1938 and subsequent amendments. *See, e.g.*, the references to the involvement of the Association in the 1954 pesticide amendments to the Act, cited in the Government's Petition (Pet. 11-12 n.5).

SUMMARY OF ARGUMENT

Almost fifty years after the enactment of the Federal Food, Drug, and Cosmetic Act of 1938 a panel of the United States Court of Appeals for the District of Columbia Circuit has announced an unprecedented interpretation of key provisions of the Act that renders a substantial portion of the American food supply adulterated and unlawful, that makes it realistically impossible for growers and food company officials to heed this Court's admonition to "insure that violations [of the Act] will not occur,"[2] and that imposes a staggering burden on the FDA to initiate and complete formal evidentiary hearings for all unavoidable contaminants in hundreds of agricultural commodities. In holding that "the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulaterated,"[3] the court rejected the agency's contemporanous, consistent, and long-standing interpretation of the Act, and in so doing cited *no* judicial, legislative, administrative, or other authority that has *ever* interpreted the Act in this manner.

The sole basis for the court's conclusion was its reading of the provision in § 406 that "the Secretary shall promulgate regulations limiting the quantity [of unavoidable or required addded poisonous or deleterious substances in food] to such extent as he finds necessary for the protection of public health."[4] Because the court interpreted the "to such extent" clause as not modifying "the pivotal word 'shall'," it concluded that the Secretary "must" promulgate regulations embodying tolerances.[5] Although the court

[2]United States v. Park, 421 U.S. 658, 672 (1975).

[3]Pet. App. 15a.

[4]21 U.S.C. § 346.

[5]Pet. App. 7a.

purported to rely upon "the clear language of the statute," its decision has the effect of writing into § 406 a safety standard for environmental contaminants, and of rendering the key adulteration standard of § 402(a)(1) totally inoperative.

In rejecting the FDA's consistent interpretation of that statutory language in favor of its own, the court found it necessary to characterize legislative history supporting the FDA's interpretation as inconclusive and to dismiss all of the relevant cases on the ground that they "do not speak to the issue at hand."[6] The opinion makes no reference to the FDA's legal and policy analysis that accompanied the agency's promulgation of the regulations under which it adopted the aflatoxin action levels at issue.

In short, the court of appeals decision hangs solely by the thread of its selective and unprecedented reading of the statutory language. We respectfully submit that the court has misread the statutory language, disregarded the statutory purpose and scheme, misunderstood the legislative history and Congressional intent, and failed to reconcile its reading of the Act with the unambiguous dictates of this Court in *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914), and *United States v. Park*, 421 U.S. 658 (1975).

[6]Pet. App. 15a.

ARGUMENT

I. THE LANGUAGE OF THE STATUTE DOES NOT SUPPORT THE HOLDING OF THE COURT BELOW THAT A SECTION 406 TOLERANCE MUST BE ESTABLISHED "IF FOOD WITH AN UNAVOIDABLE POISONOUS OR DELETERIOUS SUBSTANCE IS TO BE CONSIDERED UNADULTERATED"

The conclusion and holding of the court of appeals is succinctly stated in Part III of its opinion (Pet. App. 15a):

> [T]he FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes of 21 U.S.C. § 342(a)(1) or unsafe [sic] for purposes of 21 U.S.C. § 342(a)(2)(A), ...

This conclusion was said by the court to be based on "the language of the statute itself," which in the court's view "plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." Pet. App. 6a, 7a, 8a. On this basis the court held that "the FDA may not proceed by means of action levels rather than tolerances." Pet. App. 2a.

The court's interpretation of the "language of the statute" in § 402(a)(1), § 402(a)(2)(A), and § 406 – the operative language of which has remained essentially unchanged since enactment in 1938 – is in fact totally at odds with the wording of the statute and with the authoritative understanding and application of the statute for almost fifty years.

A. The First Clause of Section 402(a)(1) Embodies A Quantitative Rather Than An Absolute Standard of Adulteration For Added Poisonous or Deleterious Substances In Food

The beginning point is the first clause of § 402(a)(1), which provides that a food shall be deemed to be adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to health." Though written in the broadest terms, this clause in fact applies only to poisonous or delterious substances that are "added" to food. The second clause of § 402(a)(1) provides that if a subtance is not "added" to but occurs naturally in food then the food is not considered adulterated if the quantity of the substance in the food "does not ordinarily render it injurious to health." That is a separate and more lenient standard than the standard of the first clause. This Court has held that, though more stringent, the adulteration standard of the first clause is not absolute: food is adulterated only if an added poisonous or deleterious substance is present in such quantity that it might render the food injurious to health. *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914); *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, 161 (1958).

The court below plainly did not understand the centrality of the first clause of § 402(a)(1) in defining what substances added to food result in adulteration of the food. Its opinion wavers between recognizing the relevance of its own version of the first clause and ignoring it altogether. After quoting §§ 402(a)(2)(A) and 406 at the outset of Part I of the opinion as if they alone governed the adulteration of food because of the presence of added substances, the court stated in a seeming allusion to § 402(a)(1):

> Not only is it undisputed that aflatoxin is "poisonous or deleterious" and that it is an "added" substance, but the Secretary also admits facts, *see* Appellee's Brief at 4, sufficient to conclude that the presence of aflatoxin in food *may render such consumables injurious to health.* Hence, *section 342* [§ 402] would, except for the saving grace of section 346 [§ 406], *define any aflatoxin-tainted corn to be adulterated,* and such corn would therefore be banned from interstate commerce, *see* 21 U.S.C. 331(a).[7]

Standing alone, this brief passage may suggest that the court relied significantly on the Secretary's purported factual admission that any amount of aflatoxin "may render [food] injurious to health." But there was no such admission. The Government indeed "admits facts" at the cited page in the brief that support the conclusion that aflatoxin is poisonous or deleterious,[8] but neither on that page nor elsewhere in the brief or in the record does the Government admit, assert, or imply that the mere presence of any amount of aflatoxin in corn "may render it injurious to health." On the contrary, the Government's brief makes clear that the FDA's 20 ppb action level for aflatoxin in corn was its best determination of the *minimum* level at which a violation of § 402(a)(1) might be deemed to occur. One of the considerations on which the action level was

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[7]Pet. App. 4a (emphasis added). The court does not actually cite or quote § 402(a)(1) at this point, but the underlined words in the first sentence of the quoted passage are obviously a reference to and application of the operative language of the first clause of § 402(a)(1), and the underlined words in the second quoted sentence are clearly intended to state that corn containing aflatoxin is adulterated under § 402(a)(1), in the absence of a § 406 tolerance.

[8]Appellee's Brief in the court of appeals ("Appellee's Brief"), at 4.

said to be based was the FDA's conclusion that "[d]irect consumption by humans of corn containing more than 20 ppb of aflatoxin may be injurious to their health." Appellee's Brief at 7. More specifically, the Government stated in its brief that "if corn contains *fewer* than 20 ppb aflatoxin . . . , FDA cannot responsibly recommend regulatory action against the corn because the corn is not adulterated within the meaning of § 402(a)(1)." Appellee's Brief at 34 (emphasis in original). At aflatoxin levels below 20 ppb, *"FDA simply does not have the evidence to prove that the corn may be injurious to health." Id.* (emphasis added).

Thus, far from admitting that the mere presence of aflatoxin in corn would render it adulterated under § 402(a)(1), the Government consistently emphasized that the FDA could *not* establish that 20 ppb aflatoxin or less in corn "may render it injurious to health." There is thus no factual basis in the record for the conclusion that the "presence of aflatoxin in food may render such consumables injurious to health," or the ultimate conclusion that § 402(a)(1) would "define *any* aflatoxin-tainted corn to be adulterated." Pet. App. 4a (emphasis added).

Later on, in Part II of its opinion the court seems to regard § 402(a)(1) as irrelevant. Its attention invited to *Lexington Mill* and *Flemming* and their holding that § 402(a)(1) requires for adulteration a quantity of a contaminant that might be injurious to health, the court distinguished those decisions of this Court on the ground that it is not § 402(a)(1) but § 402(a)(2)(A) "that defines as 'adulterated' food which is unsafe within the meaning of [§ 406]; *Lexington Mill* and *Flemming* thus do not speak to the issue at hand." Pet. App. 15a.

But then, in summing up its conclusion in Part III of the opinion, the court brought § 402(a)(1) back into the picture, and in such a way as to indicate that the court considered § 402(a)(1) to be an absolute standard banning foods containing any amount of a contaminant in the absence of a tolerance. The court there said that it had concluded that "the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulaterated for the purposes of 21 U.S.C. § 342(a)(1) [§ 402(a)(1)] . . . ." Pet. App. 15a.

This vacillation of the court between relying on and discounting § 402(a)(1) as a basis for its invalidation of action levels should not be allowed to obscure the facts that the mere presence of aflatoxin does not automatically render corn adulterated under § 402(a)(1) and that a 20 ppb action level for aflatoxin in corn cannot be regarded as invalid under § 402(a)(1) as a matter of law. Whether §§ 402(a)(2)(A) and 406 provide an independent basis for concluding that all aflatoxin-tainted corn is adulterated in the absence of a § 406 tolerance — as the court suggests in attempting to distinguish *Lexington Mill* — is addressed in the following section.

B. Sections 402(a)(2)(A) and 406 Do Not Prescribe An Adulteration Standard For Unavoidable Added Poisonous Substances For Which No Tolerance Has Been Adopted

The first clause of § 402(a)(1), then, prescribes the general statutory safety standard for foods containing added poisonous or deleterious substances, providing that a food shall be deemed to be adulterated if such a substance is present in sufficient quantity that it might render the food injurious to health. Section 402(a)(2)(A) also applies to added poisonous or deleterious substances, but *only* when such a substance is deemed "unsafe" within the meaning of § 406. This latter section provides that an added poisonous or deleterious substance shall be deemed

"unsafe" for purposes of § 402(a)(2)(A) under only two circumstances.

Under the first clause of § 406, *any* amount of an added poisonous or deleterious substance is unsafe if it is *not* required in the production of food or is *not* unavoidable.[9] For this particular category of added substances, then, §§ 406 and 402(a)(2)(A) establish an absolute, non-quantitative standard which may be invoked by the FDA in place of § 402(a)(1) to establish adulteration of a food without the need to demonstrate in court that the quantity of the added substance might render the food injurious to health.

The second category of added poisonous or deleterious substances deemed "unsafe" under § 406 consists of those which *are* required in production or *are* unavoidable, *and* for which a § 406 tolerance has been adopted, if they are present in an amount above the tolerance. The section goes on to provide that while such a tolerance is in effect, a food containing the substance is not considered adulterated under the general adulteration standard of § 402(a)(1). This latter provision thus avoids a conflict between the case-by-case enforcement approach of § 402 (a)(1) and the substantive rulemaking approach of § 406, so that in appropriate circumstances the FDA may adopt a § 406 tolerance below, at, or above the level that would constitute adulteration under § 402(a)(1), and thereafter establish adulteration under § 402(a)(2)(A) by showing

[9]The terms "required in the production" of food, and "cannot be avoided by good manufacturing practice" are not defined in the Act or regulations. *See* 21 C.F.R. Part 109. Their scope and legislative history are discussed in Merrill, *Regulating Carcinogens in Food*, 77 Mich. L. Rev. 171, 197 n.90 (1978). The scope and applicability of these terms are not in issue in this case, since the FDA found aflatoxin to be unavoidable and that finding was not challenged by the respondents or questioned by the court of appeals.

that food contains the substance in excess of the tolerance.[10]

The language of § 406 — on which the court purports to place such reliance — does *not* prescribe a safety standard for required or unavoidable added poisonous or deleterious substances for which a tolerance has *not* been adopted. Both the wording and general scheme of the statute thus dictate that this particular category of added poisonous or deleterious substances is governed by the quantitative "may render" standard of § 402(a)(1), and that §§ 402(a)(2)(A) and 406 have applicability only to foods containing substances that are explicitly deemed "unsafe" within the meaning of § 406.

The court below of course reached a contrary conclusion, focusing almost exclusively on "[t]he presence of the critical word 'shall' " in § 406, which it says "plainly *suggests* a directive to the Secretary to establish a tolerance, if a food with an unavoidable poisonous or deleterious substance is to be considered unadulterated." Pet. App. 6a (emphasis added). The FDA contended that the decision to proceed by action levels under § 402(a)(1) rather than tolerances under § 406 lies within the Secretary's discretion, since he is directed to promulgate regulations "limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health." In rejecting this contention of the FDA, the court concluded

[10]Tolerances under § 406 limit the quantity of the substance "to such extent as [the Secretary] finds necessary for the protection of public health," taking "into account the extent to which the use of the substance is required or cannot be avoided in the production of each such article, and other ways in which the consumer may be affected by the same or other poisonous or deleterious substances." The FDA thus has considerable discretion in prescribing tolerance levels under § 406, subject to the substantial evidence standard of § 701(f)(3). 21 U.S.C. § 371(f)(3).

"from the structure of the sentence" that the "to such extent" clause does not modify "shall" but rather "explains the standard that the Secretary is to employ in setting the tolerance."[11]

The court of appeals purported to find support for its reading of § 406 in the "overall structure" of the section, and in particular in the second sentence, which in the court's words provides "that, when a regulation establishing a tolerance is in effect, such food will not be considered adulterated." Pet. App. 7a. On this basis, the court concluded:

> Since the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce.

The court's paraphrases of the second sentence of § 406 in these quoted excerpts omit the concluding phrase of that sentence – "within the meaning of clause (1) of section 402(a)."[12] This omission is apparently not inadver-

[11]Pet. App. 7a. Standing by itself the structure of this sentence could arguably support either the FDA's or the court's interpretation. But it is difficult to see how the court could be so assured that the FDA's long-standing interpretation is impermissible and "flies in the teeth of Congress' clear intent." Pet. App. 6a. The issues of Congressional intent and the court's obligation to give deference to the FDA interpretation are addressed at pp. 17-21 and 21-23, *infra*.

[12]The second sentence reads in full: "While such a regulation is in effect limiting the quantity of such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a)." As previously noted, this provision assures that when a tolerance has been adopted, §§ 402(a)(2)(A) and 406 will govern rather than the case-by-case standard of § 402(a)(1). *See* text and note at p. 10, *supra*.

tent for when the court earlier quoted § 406 at length in its opinion, it elided from the second sentence the phrase "within the meaning of clause (1) of section 342(a) of this title." Pet. App. 4a. This suggests that the court simply does not fully understand the statutory scheme. The ultimate standard for a food is adulteration. The mere existence of a formal tolerance level for a contaminant does not, of course, prevent a food containing any quantity of the contaminant from being adulterated. If the quantity exceeds the tolerance level, the contaminant is "unsafe" under § 406 and therefore the food is adulterated under § 402(a)(2)(A).

The court's misunderstanding of § 406 in this regard may have contributed to the basic logical fallacy in its statutory interpretation. From the major premise, "the existence of a regulation operates to render the food legally unadulterated" (if a tolerance, then food not adulterated) the court concluded that the *absence* of a tolerance implies the food *is* adulterated. The court's reasoning is doubly flawed. Its major premise is wrong because it misstates the statute. And the laws of logic provide that denial of the antecedent in a major premise does not imply denial of the consequent.[13] Thus both logic and the language of the statute clearly support the conclusion that if no tolerance is in effect for an unavoidable added substance, § 406 has no application, and the general safety standard of § 402(a)(1) governs.

The court of appeals interpreted § 406 as if it provided that an added unavoidable poisonous or deleterious sub-

[13]An argument of this form (if A, then not B; not A, therefore B), is said to commit the Fallacy of Denying the Antecedent. Copi, *Introduction to Logic*, 234, 274 (1972).

stance shall be deemed unsafe *unless* a tolerance is in effect. But when Congress has intended to impose such a requirement, it has done so explicitly, not by implication or "suggestion." Sections 408(a), 409(a), and 706(a) provide that a pesticide, or a food additive, or a color additive shall be deemed to be unsafe "unless" a lawfully prescribed tolerance or exemption is in effect.[14] The wording of each of these provisions indicates that they were to some extent modeled on the language of § 406, but in each case the "unless" clause – not present in § 406 – was added. The court of appeals opinion does what Congress deliberately decided not to do – interpret § 406 as if it read exactly like §§ 408(a), 409(a), and 706(a).

Further, the court's interpretation of § 406 has the effects of rendering totally inoperative the Act's basic safety standard in § 402(a)(1). Sections 402(a)(2)(A) and 406 establish an absoltue ban for added poisonous or deleterious subtances that are *not* required or unavoidable, so that the "may render" standard of § 402(a)(1) need have no application to such substances. And §§ 402(a)(2)(A) and 406 explicitly displace § 402(a)(1) when a tolerance has been adopted for an added poisonous or deleterious substance that *is* required or unavoidable. That leaves the first clause of § 402(a)(1) to apply *only* to unavoidable or required added poisonous or deleterious substances for which a tolerance has *not* been prescribed. If the court below is correct, then this latter category is also governed by §§ 402(a)(2)(A) and 406, and the first clause of § 402(a)(1) has been totally inoperative since it and § 402

[14]21 U.S.C. §§ 346a(a), 348(a), 376(a). These pre-market regulatory schemes were enacted by Congress between 1954 and 1960. The three categories of substances are explicitly excepted from § 402(a)(2)(A).

(a)(2)(A) were enacted together in 1938.[15] The court's interpretation clearly offends the "well-settled rule that all parts of a statute, if possible, are to be given effect." *American Textile Manufacturers Institute, Inc. v. Donovan,* 452 U.S. 490, 513 (1981); *Fidelity Federal Savings & Loan Ass'n. v. de la Cuesta,* 458 U.S. 141, 163 (1982).

C. Respondents' Interpretation Of The Act Concedes That The Holding Of The Court Of Appeals Is In Error

In their brief in opposition to the Government's Petition, respondents conceded that § 402(a)(1) continues to apply to added poisonous or deleterious substances "for which the FDA has not yet issued a tolerance." Respondents' Brief 9. This assertion is of course directly contrary to the holding of the court of appeals that the FDA is required to establish tolerances "in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes" of § 402(a)(1). Pet. App. 15a. It is respondents' acknowledgement of the literally impossible practical situation that the decision they urged on the court of appeals would create.

Under the respondents' new theory the first clause of § 402(a)(1) applies to an added poisonous or deleterious substance "until sufficient time has elapsed for the agency to comply with the procedures" of § 701(e). Respondents' Brief 9. Respondents cite *no* statutory language, legislative history, or other authority to support their view of

[15]The legislative history of these provisions indicates that Congress clearly envisioned § 402(a)(1) as having independent substantive effect. *See* p. 18, *infra.*

§ 402(a)(1) as merely a transitional provision, and they do not explain whether, or at what point, § 402(a)(1) ceases to apply if the FDA has not adopted a § 406 tolerance for a known contaminant.[16]

Further, the respondents' new statutory theory is inconsistent with the kind of suit that they filed against the FDA. What they should have done under this theory was initially to petition the FDA to adopt a § 406 tolerance for aflatoxin pursuant to the agency's procedural regulations,[17] and then seek review in court if the FDA denied that petition. Respondents did not follow that course. Instead, they filed a complaint in the district court challenging the validity of the FDA action levels for aflatoxin on legal and procedural grounds. The only issue reached by the court of appeals in reviewing the district court's dismissal of respondents' complaint, and the only issue thus now before this Court, is the court's determination that the aflatoxin action levels are invalid as a matter of law because § 402(a)(1) and/or § 406 automatically render foods containing any amount of aflatoxin adulterated in the absence of a § 406 tolerance.

That unprecedented interpretation of the statute finds no support in the language of the Act; the court of appeals opinion cites no authority that has ever interpreted the Act in this manner; and even respondents now in effect concede that the court of appeals' reading of the statute was in error.

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[16]Congress has frequently enacted transitional provisions to apply for a specified period pending the implementation of a new regulatory program by the FDA. *See, e.g.*, 74 Stat. 404 (1960) (color additives); 72 Stat. 1788 (1958) (food additives); 68 Stat. 517 (1954) (pesticide chemicals).

[17]21 C.F.R. § 10.30.

II. THE 1938 LEGISLATIVE HISTORY OF SECTIONS 402(a) AND 406 MAKES CLEAR A CONGRESSIONAL INTENTION THAT CONTRADICTS THE READING OF THESE PROVISIONS BY THE COURT OF APPEALS

In response to the request of the parties below that the court consider the legislative history of the statutory provisions at issue, the court purported to "find little guidance in the legislative history and certainly not the clear intention necessary to counter the expression of clear language of the statute." Pet. App. 9a. The court's discussion of the legislative history focused exclusively on three documents: a 1935 Senate Report,[18] a 1937 House Committee print,[19] and the 1938 House Report on the final version of the bill.[20]

These three documents standing alone, and considered outside of the context of the five-year legislative history of the Act, may at most support the view that Congress did not make clear its intent with respect to the interpretation and application of the Secretary's authority under § 406. But if the legislative history as a whole is considered, in the light of the contemporary understanding and intent with respect to the statutory provisions, there is no room for reasonable doubt that the FDA's long-standing interpretation of §§ 402(a) and 406 accurately reflects what Congress had in mind.[21]

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[18]S. Rep. No. 646, 74th Cong., 1st Sess. (1935).

[19]House Committee on Interstate and Foreign Commerce, 75th Cong., 1st Sess., Committee Print No. 3 (August 19, 1937), *reprinted* in 81 Cong. Rec. (Appendix) 2341, 2344 (August 21, 1937).

[20]H.R. Rep. No. 2139, 75th Cong., 3d Sess. (1938).

[21]For an excellent contemporary review of the enactment of the 1938 Act, *see* Cavers, *The Food, Drug, and Cosmetic Act of 1938: The Legislative History and Its Substantive Provisions*, 6 Law & Contemp. Problems 2 (1939).

The following summary of some of the principal highlights of the five-year legislative history, together with the chart in Appendix A setting forth the development of the statutory provisions ultimately enacted as §§ 402(a) and 406, clearly demonstrates the Congressional intent in this regard:

1. The 1906 Act included no authority for the promulgation of formal tolerances for added poisonous or deleterious substances. Appendix A, item 1. The FDA did adopt informal tolerances for a number of pesticide sprays in order to advise the public of the level at which it would initiate enforcement action, but it was necessary to prove in each case that the amount in the product was such that it might render the food injurious to health. *United States v. Washington Dehydrated Food Co.*, 89 F.2d 606 (8th Cir. 1937).

2. One of the purposes of the proposed new food and drug law was to authorize the FDA to promulgate regulations prohibiting or establishing formal tolerances for specific added poisonous or deleterious substances, primarily pesticide sprays. Cavers, *supra* n. 21, at 14-15.

3. The language of the proposed statutory provisions, as well as the 1934 Senate Report on the legislation, made it quite clear that these tolerances or prohibitions were authorized and not required in every case, and that the general adulteration standard would "apply to foods containing added poisons for which no tolerance had been set and which for that reason would not be subject to section 3(a)(2)," the legislative forerunner of § 402(a)(2). Appendix A, item 2.

4. Subsequent changes in wording further refined these provisions in the 74th and first session of the 75th Congress, but they retained the basic approach of authorizing

and not requiring the adoption of tolerances.[22] Nowhere in the hearings, reports or debates was it ever suggested that the FDA was required to issue prohibitions or tolerances for all added poisonous substances, or that its failure to issue tolerances would automatically render foods adulterated if they contained any amount of such substances.

5. The wording changes incorporated by the House committee in these provisions in 1938 were not explained in the Report or in the debates, but there was no indication that the change in § 406 from "is authorized to" to "shall" was intended to reorient the previously consistent Congressional intent, and thereby totally displace the operative effect of § 402(a)(1). Indeed, the committee Report stated, as had its predecessors, that "the establishment of tolerances is authorized." Appendix A, item 8. At the same time, the committee added to § 406 the sentence rendering § 402(a)(1) inapplicable when a tolerance had been adopted, in order to avoid the possibility of a conflict between the two sections. If the change from "is authorized to" to "shall" had been intended to have the effect asserted by the court of appeals, rendering any such substance unsafe in the absence of a tolerance, the committee surely would have added a sentence to that effect — as Congress did some years later in §§ 408(a), 409(a), and

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[22]Appendix A, items 3-7. One of these changes, made by the House committee in 1936, revised the second clause of then § 305 [predecessor to § 406] as follows: "but when such substance is so required or cannot be so avoided, the Secretary is authorized to promulgate regulations limiting the quantity therein or thereon *to such extent as he finds necessary for the protection of public health.*" Appendix A, item 5. The "to such extent" clause was thus added at the end of the sentence when the section still "authorized" the promulgation of regulations, and clearly was intended to control *whether* a tolerance should be adopted and the level at which it should be set.

706(a) — rather than leave such a far-reaching result to be implied or suggested.

6. One of the two or three major issues in the debate on the final bill in the House in June of 1938 concerned the procedures by which the FDA would promulgate tolerances under § 406. Cavers, *supra* n. 21 at 20-21. Congressmen from apple-producing states had been successful in writing rigorous rulemaking and judicial review provisions into the House committee bill in order to protect their constituents from unduly restrictive tolerances for pesticide sprays.[23] At no time was it suggested in the Reports or the extensive floor debates[24] that failure of the FDA to promulgate tolerances, or the invalidation of a tolerance by a reviewing court, would render adulterated all foods containing any amount of pesticide residues. Clearly the efforts to protect apple growers from unduly restrictive tolerances were premised on the universal understanding that in the absence of tolerances, the FDA would be required to proceed as it had under the 1906 Act, on a case-by-case basis by demonstrating in court that the

[23]Cavers, *supra* n. 21 at 20-21. The pros and cons of the House procedural language were set forth in the House Committee and Minority Reports. H.R. Rep. No. 2139, 75th Cong., 3d Sess. 9-12 (April 14, 1938); H.R. Rep. No. 2139, Part 2, 75th Cong., 3d Sess. 1-5 (April 21, 1938). If the committee's change from "is authorized to" to "shall" in § 406 was intended to render adulterated foods containing *any* pesticide residues unless a tolerance were adopted, the majority committee members would have referred to this fact in the Report and in the debates, in view of their preoccupation with the effect of § 406 on the use of pesticides by apple growers.

[24]*See, e.g.*, 83 Cong. Rec. 7774 (1938) (including statements by the committee Chairman that the Secretary "shall have *authority* after proper hearing to prescribe the extent of spray residue that shall be permissible," and that he would have "the *right* after proper hearings to adopt regulations prescribing limits") (emphasis added); 83 Cong. Rec. 7782-85, 7891-98 (1938); 83 Cong. Rec. 9096-9100 (1938) (House debate on the Conference Report).

quantity of the residue might render the apples injurious to health under § 402(a)(1).[25]

The interpretation of § 402(a)(1), § 402(a)(2)(A), and § 406 espoused by the court below is thus totally at odds with the statute as it was proposed, explicitly explained in the initial Senate Report, debated, and enacted by Congress in 1938, and as it has been consistently interpreted and applied by the FDA since that time.

III. THE COURT OF APPEALS DISREGARDED ITS OBLIGATION TO GIVE "CONSIDERABLE DEFERENCE" TO THE AGENCY'S LONG-STANDING INTERPRETATION OF THE ACT

Nowhere in the opinion below does the court acknowledge the teaching of this Court that "an agency's construction of a statute it is charged with enforcing is entitled to deference if it is reasonable and not in conflict with the expressed intent of Congress." *United States v. Riverside Bayview Homes, Inc.*, 54 U.S.L.W. 4027, 4030 (Dec. 4, 1985). As stated in *Chemical Manufacturers Ass'n v. Natural Resources Defense Council, Inc.*, 105 S. Ct. 1102, 1108 (1985):

> [The] view of the agency charged with administering the statute is entitled to considerable deference; and to sustain it, we need not find that

[25]That is of course exactly what happened, as the FDA decided not to undertake the procedures necessary for promulgation of § 406 tolerances. Sixteen years later Congress enacted § 408, 21 U.S.C. § 346a, in order to establish a pre-market approval system for pesticides used in or on agricultural commodities. Section 406 was retained in the Act to continue to prohibit avoidable or unrequired added poisonous or deleterious substances, and to authorize tolerances for unavoidable or required added poisonous or deleterious substances other than pesticides on raw agricultural commodities.

> it is the only permissible construction that [the agency] might have adopted but only that [the agency's] understanding of this very "complex statute" is a sufficiently rational one to preclude a court from substituting its judgment for that of [the agency].

The court of appeals alluded to this doctrine in citing *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1566 (D.C. Cir. 1984) (*en banc*), and *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 104 S. Ct. 2778, 2781 (1984), for the proposition that if the intent of Congress is clear, the court must give effect to that intent and reject a contrary administrative construction. Pet. App. 5a, 6a. What the court did not say is that the administrative construction was *upheld* in both cases. In *Chevron* this Court described the administrative interpretation as "a reasonable policy choice for the agency to make," and reversed a decision by the Court of Appeals for the District of Columbia Circuit which "misconceived the nature of its role in reviewing the regulations at issue." 104 S. Ct. at 2783.

The court of appeals purported to rely on the "clear language of the statute" in rejecting the FDA's long-standing interpretation.[26] As demonstrated in the first section of this brief, however, the court's holding depends on its unsupported and selective interpretation of a single provision in § 406, involves reading into that section a safety standard for a category of substances that are simply not referred to in the statutory language, and requires an interpretation of § 402(a)(1) that has been squarely rejected by this Court. Surely the court of appeals "misconceived the nature of its role in reviewing the regulations at issue."

[26]Pet. App. 9a. After enactment of the 1938 Act the agency continued to rely on informal action levels under § 402(a)(1) rather than invoking the cumbersome procedures required for § 406 tolerances. *See, e.g.*, United States v. 449 Cases, etc., 212 F.2d 567, 575 (2d Cir. 1954) (including Judge Frank's persuasive dissent); United States v. Anderson Seafoods, Inc., 622 F.2d 157 (5th Cir. 1980). In 1957 the FDA stated that "the act clearly contemplates that the Government may proceed against a contaminated food under section 402(a)(1) of the act when no tolerance is effective." 42 Fed. Reg. 52818 (Sept. 30, 1977).

IV. THE COURT OF APPEALS DECISION IMPOSES AN INTOLERABLE BURDEN ON THOSE RESPONSIBLE FOR MAINTAINING AN ADEQUATE FOOD SUPPLY

In holding that the FDA must issue § 406 tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated, the court of appeals has arrived at an unprecedented interpretation of the Act that renders a very substantial portion of the food supply adulterated and thus unlawful for shipment in interstate commerce. The court below[27] and other federal courts[28] have for the most part accepted the FDA's broad reading of the word "added," so that it encompasses environmental, agricultural, industrial, or other contamination that is attributable at least in minute part to the acts of man, whether by deliberate use or accidental occur-

[27]Pet. App. 3a.

[28]United States v. Anderson Seafoods, Inc., 622 F.2d 157, 161 (5th Cir. 1980) (traces of mercury in fish from both natural and human sources regarded as "added"); Continental Seafoods, Inc. v. Schweiker, 674 F.2d 38, 43 (D.C. Cir. 1982) (salmonella in fish held to be "added" on the gorund that salmonella "can result" from insanitary processing procedures).

rence. *See* p. 6, *supra*. Further, such contamination is recognized as being ubiquitous and unavoidable for commodities raised in or procured from the natural environment. As stated by the FDA:

> The Commissioner advises that it is not possible to produce food or food ingredients that are entirely free from contamination by foreign substances or impurities.[29]
>
> * * *
>
> If a nondetectable-residue requirement were automatically applied to environmental contaminants already present in the food supply, enforcement activities could significantly disrupt the food supply.[30]

If § 406 tolerances are deemed to be the only means by which the FDA may legitimize the shipment of foods containing environmental and agricultural contaminants, as held by the court below, then there is no realistic prospect that the FDA and the food industry can reconcile the practical need to continue production and distribution of the food supply with the pronouncement of this Court that "the Act imposes [on food company officials] not only a positive duty to seek out and remedy violations when they occur but also, and primarily, *a duty to implement measures that will insure that violations will not occur.*" *United States v. Park*, 421 U.S. 658, 672 (1975) (emphasis added).

The Government's Petition documents the literal impossibility of the FDA's initiating and completing within the foreseeable future proceedings for the establishment of

[29] 42 Fed. Reg. 52814 (Sept. 30, 1977).

[30] 42 Fed. Reg. 17490 (April 1, 1977).

formal tolerances for all detectable environmental contaminants.[31] Adoption of formal tolerances only for the contaminants now subject to published action levels would take a number of years to complete. In the meantime, farmers and food company officials would be faced with the necessity of choosing between seriously disrupting the nation's food supply or intentionally exposing themselves to criminal prosecution.

CONCLUSION

For the foregoing reasons, the decision of the court below should be reversed.

Respectfully submitted,

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[31] Pet. 15-16. The court below was apparently unaware of the protracted rulemaking procedures that must be observed in the promulgation of § 406 tolerances, for it refers to the plaintiffs' suit as one to require the FDA to adopt "by way of notice-and-comment rulemaking" formal tolerances as opposed to informal action levels. Pet. App. 2a. Tolerances under § 406 may of course be adopted only pursuant to the complex and protracted procedures prescribed in § 701(e).

APPENDIX A

Summary of the Legislative History Of Sections 402(a)(1) and (2) and 406
Of The Federal Food, Drug, and Cosmetic Act of 1938,
21 U.S.C. §§ 342(a)(1) and (2), 346, 52 Stat. 1046, 1049
(*Underlining* and ~~*interlining*~~ indicate changes from previous version)

Bill And Date	Adulteration Defined [enacted as §§ 402(a)(1) and (2)]	Tolerances For Poisonous Substances [enacted as § 406]
1. Federal Food and Drug Act of 1906 (34 Stat. 768)	"SEC. 7. [F]or the purposes of this Act an article shall be deemed to be adulterated: . . . In the case of food: . . . Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health."	No comparable provision.
	COMMENT: The 1906 Act applied only to "added" poisonous or deleterious ingredients, not to natural constituents of food. It contained no provision for the promulgation of tolerances for poisonous or deleterious substances.	
2. S. 2800 (as introduced, 73d Cong., 2d Sess., Feb. 2, 1934 and as reported to the Senate, S. Rep. No. 493, 73d Cong., 2d Sess. 3-4, March 15, 1934)	"SEC. 3. A food shall be deemed to be adulterated – "(a)(1) If it bears or contains any poisonous or deleterious substance which may render it dangerous to health; or (2) if it bears or contains any added poisonous or added deleterious substance prohibited, or in excess of the limits of tolerance prescribed, by regulations as provided by sections 10 and 22; . . . ."	"SEC. 10 (a) If an added poisonous or added deleterious substance in or on food . . . is or may be injurious to health, the Secretary is hereby authorized to promulgate regulations . . . prohibiting such added substance in or on any food . . . or establishing tolerances limiting the amount therein or thereon, for the protection of public health, taking into account the extent to which the use of such substance is required in the production of such food . . . ."
	COMMENT: In explaining these provisions, the Senate Report stated that: "Paragraph 3(a)(1) . . . applies to foods which by reason of the poisonous or deleterious constituent may be dangerous, irrespective of whether that constituent is added by man or put there by nature . . . . *It would also apply to foods containing added poisons for which no tolerance had been set and which for that reason would not be subject to section 3(a)(2).*" (Emphasis added).	

Bill And Date	Adulteration Defined [enacted as §§ 402(a)(1) and (2)]	Tolerances For Poisonous Substances [enacted as § 406]
3. S. 5 (as introduced, 74th Cong., 1st Sess., Jan. 3, 1935)	§ 301(a)(1) and (2) – *no change* from S. 2800, § 3(a)(1) and (2), in 73d Congress.	§ 304(a) – *no change* from S. 2800, § 10(a), in 73d Congress.
	COMMENT: The 74th Congress started out with the bill as it had been reported by the Senate committee in the 73d Congress.	
4. S. 5 (as reported to the Senate, S. Rep. No. 646, 74th Cong., 1st Sess., May 13, 1935; and passed by the Senate, 79 Cong. Rec. 8356, May 28, 1935)	"SEC. 301 A food shall be deemed to be adulterated – (a)(1) if it bears or contains any poisonous or deleterious substance which may render it dangerous to health; or (2) if it bears or contains any added poisonous or added deleterious substance *which may render it injurious to health, or which is* prohibited *by § 304*, or in excess of the limits of tolerance prescribed by regulations as provided by §§ 304, 701, and 703."	"SEC. 304. (a) To safeguard the public health, no poisonous or deleterious substance shall be added to any food except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice; but when such substance is so required or cannot be so avoided, the Secretary is authorized, for the protection of public health, to promulgate regulations, as provided by sections 701 and 703, limiting the quantity therein or thereon . . . ."
	COMMENT: The 1935 Senate-passed version of S. 5 retained the basic approach of the earlier bills, but made several key modifications. The "dangerous to health" standard was retained for naturally occurring ingredients in § 301(a)(1). Section 301(a)(2) was revised to incorporate the "may render injurious to health" standard of the 1906 Act for "added" substances, unless they were prohibited by § 304. Section 304 was rewritten so that any added poisonous substance would be prohibited unless it was required or unavoidable; as in the earlier bills, the Secretary was "authorized" to promulgate tolerances, but now only for required or unavoidable substances.	

Bill And Date	Adulteration Defined [enacted as §§ 402(a)(1) and (2)]	Tolerances For Poisonous Substances [enacted as § 406]
5. S. 5 (as reported to the House, H. Rep. No. 2755, 74th Cong., 2d Sess., May 22, 1936)	"SEC. 301. A food shall be deemed to be adulterated – (a)(1) if it bears or contains any poisonous or deleterious substance which may render it dangerous to health; or (2) if it bears or contains any added poisonous or added deleterious substance which may render it injurious to health, or which is *unsafe within the meaning of* section *305*, or in excess of the limits of tolerance prescribed by regulations as provided by section *305*."	"SEC. 304 *305*. (a) ~~*To safeguard the public health, no*~~ *Any* poisonous or deleterious substance ~~*shall be*~~ added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice *shall be deemed to be unsafe for purposes of the application of section 301(a);* but when such substance is so required or cannot be so avoided, the Secretary is authorized, ~~*for the protection of public health,*~~ to promulgate regulations ~~*as provided by sections 701 and 703,*~~ limiting the quantity therein or thereon *to such extent as he finds necessary for the protection of public health* . . . ."
	COMMENT: The 1936 House Report did not elaborate upon the indicated revisions, except to note that §§ 301(a)(2) and 305 were revised to speak in terms of "unsafe" rather than a prohibition, apparently out of concern as to the reach of Congress' power over commerce. The limitation on the Secretary's authority to promulgate tolerances was added – "to such extent as he finds necessary for protection of public health." At this point it was clear that this limitation controlled both *whether* a tolerance should be adopted *and* the level at which it would be set.	
6. S. 5 (as introduced, 75th Cong., 1st Sess., Jan. 6, 1937)	§ 11(a)(1) and (2) – *no change* from § 301(a)(1) and (2) of S. 5 as reported to the House in the 74th Congress.	§ 15(a) – *no change* from § 305 of previous House bill, except that "contaminating" was added to precede "poisonous."

Bill And Date	Adulteration Defined [enacted as §§ 402(a)(1) and (2)]	Tolerances For Poisonous Substances [enacted as § 406]
7. S. 5 (as reported to the Senate, S. Rep. No. 152, 75th Cong., 1st Sess., March 8, 1937; and passed by the Senate, 81 Cong. Rec. 2009, 2010, 2019, March 9, 1937)	"§ 11. A food shall be deemed to be adulterated – (a)(1) if it bears or contains any poisonous or deleterious substance which may render it dangerous to health; or (2) if it bears or contains any added poisonous or added deleterious substance which may render it injurious to health, or which is unsafe within the meaning of section 305, ~~*or in excess of the limits of tolerance prescribed by regulations as provided by section 305*~~."	§ 15(a) – no change, except for adding at the end of the first sentence the words "and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of section 11(a)."
	COMMENT: The 1937 Senate-passed bill left essentially unchanged the bill as it had been reported out by the House committee in the previous Congress. It remained clear that the first clause of § 11(a)(2) applied to required or unavoidable substances for which no tolerance had been set.	
8. S. 5 (as reported to the House, H. Rep. No. 2139, 75th Cong., 3d Sess., April 14, 1938, passed by the House, 83 Cong. Rec. 7903, June 1, 1938; and approved by the President, Pub. L. No. 717, 75th Cong., June 25, 1938)	"SEC. 402. A food shall be deemed to be adulterated – "(a)(1) If it bears or contains any poisonous or deleterious substance which may render it ~~*dangerous*~~ *injurious* to health; *but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health;* or (2) if it bears or contains any added	"SEC. 406. (a) Any ~~*contaminating*~~ poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402(a); but when such substance is so required or cannot be so avoided, the Secretary *is* ~~*authorized to*~~ *shall* promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the

Bill And Date	Adulteration Defined [enacted as §§ 402(a)(1) and (2)]	Tolerances For Poisonous Substances [enacted as § 406]
	poisonous or added deleterious substance which ~~may render it injurious to health, or which~~ is unsafe within the meaning of section 406; . . . ."	limits for fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402(a). *While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a) . . . ."*

COMMENT: The House committee made a number of wording revisions throughout the bill. It revised § 402(a)(1) by changing "dangerous" to "injurious," thus moving from § 402(a)(2) the "may render injurious to health" standard applicable to "added" substances. The committee added to § 402(a)(1) a new "ordinarily" injurious standard for not added substances. Section 402(a)(2) was thus left to deal solely with "unsafe" substances under § 406. In this latter provision "shall" was substituted for "is authorized to," and a new second sentence was added to make clear that § 402(a)(2) controlled rather than § 402(a)(1) *when a tolerance had been prescribed.* (In a number of other places throughout the bill the committee substituted "shall" for "is authorized to." In §§ 401 and 404, for example, it remained clear that the Secretary was to adopt regulations *if* he made the prescribed finding or judgment.)

None of these changes were elaborated upon in the Report; but like all previous reports it stated that under § 406 "the establishment of tolerances is authorized." H. Rep. No. 2139, 75th Cong., 3d Sess. 6 (April 14, 1938).